UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	§	**CASE NO. 15-mc-_____**
	§	**Principal case pending in the United States District Court for the District of Massachusetts, Case No. 1:13-MD-2428-DPW**
THIS DOCUMENT RELATES TO ALL CASES	§	

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL FILED BY THE PLAINTIFFS' EXECUTIVE COMMITTEE APPOINTED BY THE COURT IN MDL NO. 2428

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I. INTRODUCTION

On November 6, 2014, the Plaintiffs' Executive Committee ("PEC") in MDL No. 2428 (the "GranuFlo Litigation") obtained from the United States District Court for the District of Massachusetts a Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action ("Subpoena") for service on the International Journal of Nephrology, Hindawi Publishing Corporation, 410 Park Avenue, 15th Floor, #287 pmb, New York, NY 10022 (hereinafter referred to as the "Journal") , which commanded the Journal to produce documents on December 6, 2014 in accordance with the Schedule A attached to the Subpoena. A copy of the Subpoena and Schedule A thereto is attached hereto as Exhibit "1." The Subpoena was served on November 13, 2014 at the United States' business location of the Journal, 410 Park Avenue, 15th Floor, #287pmb, New York, NY. The Affidavit of Service shows that service was made on the Journal's authorized agent, Allie Hernandez. *See,* Affidavit of Service attached hereto as Exhibit "2."

At the time of the issuance of the Subpoena on November 6, 2014, the PEC also served a Notice of Deposition Subpoena Duces Tecum in the GranuFlo Litigation for the production of the documents requested in the Subpoena. The return date for the production of the documents was December 6, 2014, to occur at the Boston law offices of Kreindler & Kreindler LLP, Plaintiffs' Lead and Liaison Counsel in the GranuFlo Litigation. A copy of Plaintiffs' Notice of Deposition Subpoena Duces Tecum is attached hereto as Exhibit "3."

On November 27, 2014, Mr. Mohamed Hamdy, purportedly the Chief Operating Officer of Hindawi Publishing Corporation, wrote a letter to Kreindler & Kreindler LLP (the letter is hereinafter referred to as the "Hamdy letter") acknowledging that the Subpoena had been received in New York and that it was forwarded to him in Cairo, Egypt and that he was refusing

to comply with the Subpoena because: 1) the PEC was required to proceed in accordance with Egyptian law and 2) that the information that the PEC seeks is confidential and protected by a journalist privilege, citing to and providing a copy of a decision entered in *In re: Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, Civil Action No. 08-mc-10008-MLW (Dkt. 17, April 1, 2008) (hereinafter referred to as the "Bextra Opinion."). A copy of the Hamdy letter with the Bextra Opinion is attached hereto as Exhibit "4."

For the foregoing reasons, the PEC requests this Court to compel the Journal to produce the documents requested in the Subpoena. However, in the alternative, because the instant dispute arises out of a Multidistrict Litigation matter that has been pending for several years before the presiding judge for the GranuFlo Litigation, The Honorable Douglas P. Woodlock, MDL No. 2428 (D. Mass.), the PEC has no objection to the transfer of the matter pursuant to Fed. R. Civ. P. 45(f) to Judge Woodlock's docket pending in the United States District Court for the District of Massachusetts for its resolution.

II. FACTS

This case involves dialysis products known as GranuFlo and NaturaLyte. They are acid concentrates that were approved by the United States Food and Drug Administration (hereinafter referred to as "FDA") for use in hemodialysis (technically these are considered "devices" by the FDA). Hemodialysis is a method of treating kidney disease whereby the body's kidney function is replaced by an external machine, which filters waste, removes extra fluids and balances electrolytes in the body. Many patients who undergo hemodialysis suffer from a condition known as metabolic acidosis (too much acid in the body). Thus, as part of the hemodialysis treatment, bicarbonates are introduced into the blood to act as a pH buffer and neutralize the metabolic acidosis (too much acid in the body). Thus, as part of the hemodialysis treatment,

bicarbonates are introduced into the blood to act as a pH buffer and neutralize the metabolic acidosis. However, because of certain negative chemical reactions that would occur between the bicarbonates and electrolytes if they were introduced into the blood in the same dialysate solution, an acid concentrate is added to the solution to prevent these reactions from occurring.

Yet, while the introduction of the acid concentrate has its benefits in preventing the aforementioned chemical reactions, it also causes a separate and distinct reaction to occur in the body upon reaching the liver. Specifically, the acid and/or acetate contained within the acid concentrate is converted into bicarbonates by the liver, which in turn increases the bicarbonate levels in the blood. Thus, a person undergoing hemodialysis receives bicarbonates from two sources: (1) the bicarbonate solution introduced during dialysis; and (2) the acid concentrate when it reaches the liver. GranuFlo and NaturaLyte are acid concentrates manufactured, marketed and sold by the Defendants is this Multidistrict litigation case, to be used in hemodialysis. While most acid concentrates on the market, including NaturaLyte, contain 4 mEq/L of acetic acid, GranuFlo is a unique acid concentrate in that it is composed of 8 mEq/L of sodium diacetate (4 mEq/L of acetic acid and 4 mEq/L of sodium acetate).

On July 12, 2012 the United States Food and Drug Administration ("FDA") issued a Class I recall of Defendants' Granuflo and Naturalyte.[1] A Class I recall is a recall of dangerous or defective products that predictably could cause serious health problems or death; it is the most serious recall that can be issued by the FDA. The FDA's recall was based on its investigation (and Defendant's own documents) that found an increased risk of metabolic alkalosis, cardiopulmonary arrest, cardiac arrhythmia, hypotension, hypokalemia, hypoxemia and

[1] The Defendants in the GranuFlo Litigation MDL case are the manufacturer Fresenius Medical Care North America ("FMCNA") (a vertically integrated company which also owns and operates the largest number of dialysis centers in the United States), its related United States entities and German-based parent companies. A more thorough statement of the facts is set forth in the Master Complaint filed in the GranuFlo MDL Litigation, found on-line at: http://www.mad.uscourts.gov/worcester/MDL2428/MDL2428.htm.

hypercapnia associated with the use of Defendants' GranuFlo and/or NaturaLyte. In part, the FDA's action was in response to the results of a study performed by the Defendants, conducted by their in-house epidemiologist and then-Chief Medical Officer, Dr. Raymond Hakim, based on data which the Defendants had in their possession in November 2011 (the "November 2011 Study").

Additionally, not only did the FDA investigations reveal the increased health risk associated with the use of Defendants' GranuFlo and/or NaturaLyte, but it also further revealed that Defendants have been aware of said increased health risks since as early as 2004 (perhaps even earlier), and that they were intentionally concealing this information from doctors, dialysis clinics, healthcare providers and the public.

However, after the results of the November 2011 Study became known, Defendant FMCNA fired Dr. Hakim and thereafter engaged in damage control efforts to disavow the November 2011 Study. The document request at issue that is attached to the Subpoena seeks information about an article published in the Journal, titled "Associates of Cardiopulmonary Arrest in the Perihemodialytic Period" (published November 4, 2014) and attached as Exhibit "A" to Schedule "A" of the Subpoena (the "Article"). The Article at issue is one of the efforts by Defendants to distance themselves from the November 2011 Study, i.e., purportedly it is a reanalysis of the November 2011 Study data. The PEC believes the Article is a litigation-driven effort orchestrated by Defendants to undermine the November 2011 Study. The Article and its underlying work contain many flaws that actually caused it to be rejected for publication by five serious science journals. Indeed, it was only the Journal that is the subject of this Motion, an "open access," pay-for-publish journal based in Egypt that accepted the Article for publication.

It is noteworthy that four of the authors of the Article (Ms. Nien-Chen Li; Ms Shu-Fang Lin; Dr. Jeffrey Hymes and Dr. Eduardo Lacson, Jr.) are employees of FMCNA. One other author (Dr. Steven M. Brunelli) is an employee of DaVita Clinical Research, but has also received speaking honoraria from Defendant FMCNA. One author, Jennifer E. Flythe, does not state in the credits to the Article that she has any conflict of interest in the form of being an employee of any of the Defendants in the case, but she does reveal that she has received speaking honoraria from Dialysis Clinic, Incorporated.

The subject matter of the Article clearly is relevant to this litigation. As noted above, the litigation involves hemodialysis, and the suffering of cardiopulmonary arrest. The title of the Article is, as noted, "Associates of Cardiopulmonary Arrest in the Perihemodialytic Period." The Article discusses causes of cardiopulmonary arrest in patients undergoing hemodialysis. Data was obtained from patients receiving their hemodialysis at facilities of Defendant FMCNA. The authors include employees of Defendant FMCNA. It appears to the PEC that the Article is the Defendants' litigation-driven effort to undo or otherwise dilute the results of the November 2011 Study.

The connection between the subject matter of the Article and this GranuFlo Litigation could not be clearer. Yet what the PEC does not know and does not have access to without receiving documents requested in the Subpoena are the reasons why and manner how the Article came to be published in the precise way it was, or financial information about the payments made to or from the authors.

The Journal has been subpoenaed because, *inter alia,* the PEC believes that it would or should have documents identified in the Requests For Production of Documents (Schedule A to the Subpoena; Exhibit 1 hereto), to wit, documents relating to the drafting and editing of the

Article; documents relating to the submission and review and publication of the Article in the Journal; documents by and between the Journal and the authors of the Article; documents relating to the guidelines, conditions of acceptance, and fees for publication in the Journal; documents between the Journal and with peer reviewers; and documents relating to interactions by the Journal and the Academic Editor for the Article, David B. Kershaw, M.D. It is the PEC's belief that the Article was rejected for publication by certain other journals and to the extent that the Journal may have any information about that occurrence, such as receipt by the Journal of drafts of a submission that were rejected by other journals, or documents with suggestions by the Journal for changes to the submission in order for it to be accepted for publication by the Journal as the Article, are all important for the PEC to receive. Moreover, the PEC does not have access to these internal documents from other sources than from the Journal.

The PEC has requested that Defendant FMCNA produce documents related to the Article but being that Defendant and the Journal are in different postures relating to the Article, it is unlikely that Defendant FMCNA will have all of the types of documents that the PEC seeks from the Journal. This is because the Journal is in the unique position of being the publisher of the Article, and likely therefore to have had direct contact with the Academic Editor and the other authors that did not involve communications that included Defendant FMCNA. Of course, were the documents to reveal that Defendant FMCNA was involved first hand in the internal thinking of the Journal in evaluating the material submitted for publication, and resolving any issues relating to the final content of the Article prior to publication in the Journal, that information should be produced and disclosed to the PEC.

At this point in time in discovery in the MDL Litigation, it appears to the PEC that Defendant FMCNA, although the employer of some of the authors of the Article and having paid

honoraria to another author does not appear to possess the kinds of documents the PEC seeks from Journal. Indeed, the PEC has received a custodial file of documents from one FMCNA employee/co-author, Dr. Eduardo Lacson, Jr., and the PEC's review of those documents does not reveal the production of all documents that likely exist and would be responsive to the Subpoena served on the Journal. Moreover, regardless of what FMCNA might otherwise produce as part of general discovery in the MDL Litigation, there is no prohibition against the PEC seeking evidence from other sources. Ordering the production of documents by the Journal will likely provide additional information as set forth above, as well as enable the PEC to confirm that the PEC has received all of the evidence on the issue, and also enable the PEC to perform an audit of the completeness of the production that FMCNA makes.[2]

For the sake of further disclosure, the PEC informs the Court that it has sought documents from another author of the Article, Dr. Jennifer E. Flythe, who as noted above, does not reveal any direct connection with Defendants in the Conflict of Interests disclosure at the end of the Article. As for the efforts to obtain documents from Dr. Flythe, she has produced various documents relating to her copies of emails and communications relating to the drafting of the Article. While her document production has revealed that the Article was rejected for publication by multiple journals, her production does not appear to include all documents that likely exist relating to the interactions that the Journal had with the authors, or with Dr. Kershaw in his capacity as Academic Editor.[3]

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[2] The data used in the Article is comprised mostly of medical information about Plaintiffs and/or their decedents in the GranuFlo/NaturaLyte Litigation. The PEC expects to receive the clinical/medical data from Defendants in their document production.

[3] The PEC also discloses that it served a subpoena on Dr. Kershaw, the Academic Editor for the Article. Dr. Kershaw ignored the Subpoena served on him, making no response whatsoever and not even contacting the PEC about it. No motion to quash or motion for protective order was filed by Dr. Kershaw. As a result, the PEC has instituted a miscellaneous action in the United States District Court for the Eastern District of Michigan to compel Dr. Kershaw to comply with the Subpoena served on him, and to hold him in contempt until he complies. A hearing

As noted, Dr. Flythe's production reveals that the Article was rejected for publication by many journals because it contains numerous flaws and is unscientifically sound. The Journal however, is an "open access" journal based in Egypt that has less stringent standards for accepting an article for publication. A primary issue in the GranuFlo Litigation is the association between cardiopulmonary arrest (CPA) and high serum bicarbonate levels. Employees of FMCNA, in particular the head medical director Dr. Lazarus and the author of the November 2011 Study, Dr. Hakim, performed internal research for FMCNA over many years demonstrating an association between cardiopulmonary arrest (CPA) and high serum bicarbonate levels. But with the institution of the GranuFlo Litigation, FMCNA has chosen to criticize the results of the November 2011 Study, publicly criticize Dr. Hakim, and has used the publication of the Article at issue in this motion as part of its onslaught to discredit the November 2011 Study.

We believe that the Journal should be compelled to produce the documents requested. It is the Journal that published the Article after its rejection for publication by multiple other journals and it is a Journal that is an "open access" pay for publish type of journal that is based in a foreign country. When an Article is rejected for publication on multiple occasions, and the authors have to resort to the type of Journal that the deponent is in order to gain publication, and where the publication is a direct attack on an objective study (the November 2011 Study) that was performed prior to litigation but is now at the heart of litigation, it is only by compelling the production of information about the publication of the Article that the truth can be learned about the scientific credibility and accuracy of the Article's findings and conclusions.

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has been set on the PEC's Motion against Dr. Kershaw for March 18, 2015. The miscellaneous matter is docketed as: *Plaintiff's Liaison Counsel v. David B. Kershaw, M.D.*, Case No. 2:15-mc-50184-GAD-APP (E. D. Mich. Filed Feb. 6, 2015) (Hon. Gershwin A. Drain). It being that the Journal and Dr. Kershaw would be in different postures viz. a. viz. the Article, the document request made to the Journal is not identical to the document request accompanying the Subpoena served on Dr. Kershaw. The PEC's Motion against Dr. Kershaw has also asked in the alternative that the matter be transferred pursuant to Fed. R. Civ. P. 45(f) to the MDL Court in Massachusetts for resolution. To date, Dr. Kershaw has not responded to the Motion to Compel, however it was filed only several days ago from this filing so the response date has not yet arrived.

III. ARGUMENT

A. The Need of the PEC for the Documents Sought by the Subpoena Outweighs the Interests of the Journal, and an Order Compelling Disclosure Will Not Impose an Undue Burden on the Journal

In determining whether the PEC is entitled to an Order compelling the production of the documents in the Subpoena, the Court should balance the need of the PEC (access to relevant information to the litigation that is not otherwise available to the PEC) against the interests of the Journal (burden and alleged journal privilege) and determine which outweighs the other. *Dart Indus. Co. v. Westwood Chem. Co.*, 649 F. 2d 646, 649 (9th Cir. 1980). Thus, a court may quash a subpoena under Federal Rule of Civil Procedure 45 when compliance would result in an "undue burden" on the non-party. Fed. R. Civ. P. 45(d)(3)(A)(iv).[4]

The PEC has established the relevancy of the requested documents to the GranuFlo Litigation. Further, the information that the PEC seeks is not available from other sources. On the other side, the Journal desires to avoid the production of the documents sought on the basis of a "journalist's privilege." However, the Article has already been published so it is not as though the entry of an Order compelling the production of the documents sought would chill or affect the publication of the Article. What the PEC seeks is documents relevant to how the Article came to be published in the manner it was published, particularly in light of the fact that numerous other journals rejected the submission for publication. To be published by the Journal, the Article presumably went through some peer review process by the Journal and various drafts of the submission undoubtedly exist. Further, the Conflict of Interest disclosure in the Article reveals a financial connection of the authors with the Defendant.

The PEC does not see how or why an Order compelling the production of information

[4] *See, e.g., In re Fosamax Products Liability Litigation*, 74 Fed. R. Serv. 3d 190 (S.D.N.Y. 2009) ("In general, third parties are afforded more sympathy in weighing the burden of discovery because they have no personal stake in the litigation.").

after a submission is published as is the case here with the Article could have any impact on the publication of a submission in the first instance. Since the concern is whether the entry of an Order might chill the publication of an article, the inquiry should be focused on whether the article has already been published. If it has, then the entry of an Order after that occurrence should not have any chilling impact. It might only be in the instance of an Order compelling disclosure *before* the publication of an article might such an Order have a chilling impact. The difference between an Order compelling pre-publication disclosure and post-publication disclosure is significant.

Nevertheless, it is speculative whether the Journal will suffer any "undue burden" if compliance with the Subpoena be ordered. The Journal did not file a Motion to Quash or a Motion for a Protective Order. Its letter response is short on information as to why compliance would be burdensome to it. When a subpoena for the production of documents is properly served, as is the case here, the party served can file objections to the subpoena or file a motion to quash. Rule 45(d)(2)(B) requires that objections "must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served." If the objections are based on privilege, they must be made, along with the claim of privilege, within the 14 day time period set forth in the rule. *See In re Dep't of Justice Subpoenas to ABC*, No. 08–MC–10253–PBS, 263 F.R.D. 66 (D. Mass. 2009).

Here, no motion to quash was filed. All that was received by the PEC was the Hamdy Letter, which does not assert that the Subpoena is facially overbroad nor offer any compromise towards the production of the documents requested. Since no motion to quash was filed it is now too late to file such a motion. A motion to quash must be made "timely." Though the rule does not define "timely," it is generally understood "to mean within the time set in the subpoena for

compliance." *Town of Grafton v. Pulte Homes of New England, LLC*, Civ. A. 12-10524-TSH, 2014 WL 2155035 (D. Mass. 2014), citing *Sterling Merch., Inc. v. Nestle, S.A.*, 470 F. Supp. 2d 77, 85 (D.P.R. 2006). *See also Estate of Ungar v. Palestinian Authority*, 451 F. Supp. 2d 607 (S.D.N.Y. 2006) ("It is well settled that, to be timely, a motion to quash a subpoena must be made prior to the return date of the subpoena.").

Even had a motion to quash been filed, the Journal would have had the burden of persuasion. *Concord Boat Corp. v. Brunswick Corp.*, 169 F.R.D. 44, 48 (S.D.N.Y. 1996). *See also John Wiley & Sons, Inc. v. Doe Nos. 1-30*, 284 F.RD. 185 (S.D.N.Y. 2012).

B. The Journal's Objection Letter Asserting a Journalist's Privilege Is Not The Equivalent of a Motion to Quash the Subpoena

While the Journal did not file a formal motion to quash, the Hamdy Letter asserts a journalist's privilege, relying on the *Bextra* Opinion. Assuming the letter objection should be evaluated as though it is the equivalent of a Motion to Quash, quashing a subpoena on the basis of journalist's privilege involves weighing the needs of the requester and the confidentiality interests of the objector, as well as the potential chilling effect on research and free speech. The Journal has not evaluated any of these matters, simply positing in the abstract that *Bextra* protects it from having to comply with the Subpoena.

Most of the case law suggests that parties seeking journal information face a hurdle of showing relevance and probative value. The PEC has met that burden. In cases ruling against disclosure, the courts appeared particularly bothered where a party subpoenaed "confidential" material from a stranger to the litigation. However, in cases where the subpoenas were enforced, the non-party status of the subpoena subject was not a decisive factor. Important in cases where production was ordered has been the fact that the research had already been published, as opposed to pre-publication disclosure of research, and that the research was likely to be relied

upon by a party to the litigation. Here, the Article has been published that the PEC does intend to rely on the discovery in the litigation.

As noted above, the Journal's publisher, Hindawi Publishing Corp., submitted a letter objection to the PEC citing to the *Bextra* Opinion. In *Bextra*, Pfizer sought documents that related to articles about Bextra and Celebrex, which were either published in the New England Journal of Medicine, or were rejected for publication. The request initially included information from the peer review process, such as peer reviewer identities and comments, however, that request was subsequently withdrawn by Pfizer. NEJM produced some responsive documents and engaged in negotiations with Pfizer regarding production. This is noteworthy, i.e., that NEJM did produce responsive documents and did engage in negotiations for the scope of additional productions. This is in stark contrast to the situation here where the Journal has refused to produce any documents, has not initiated any dialogue to meet and confer to resolve the dispute and has not demonstrated why *Bextra* is on all fours with the facts in this case so as to entitle it to protection.

Because the parties in *Bextra* engaged in some meet and confer process, the only issue left for that court was whether to compel production of the NEJM's communication with the authors. But as noted here, one of the lead authors, Dr. Flythe has been producing information to the PEC and the PEC has received some information from other authors because of their affiliation with Defendant FMCNA as part of a custodial production. So, to the extent *Bextra* relates to whether a journal's communications with authors should be protected on the basis of some privilege or confidential relationship, here, the voluntary productions that have occurred undermine the notion of such a privilege or confidential relationship.

Moreover, even with the voluntary productions by Dr. Flythe and by Defendant's employee-authors, there is a gap in the information being produced to the PEC and the PEC has no place else to turn to for that information but to the Journal.

Further, here the goal of the PEC differs from the goal of Pfizer in *Bextra*. In *Bextra*, Pfizer said it desired to show juries all of the scientific data and explain that scientists may differ over complicated issues and to use the information for impeachment purposes. Here, the PEC knows that the Article was rejected for publication by numerous other journals. It was published only by a foreign, open access, pay for publication entity, the Journal here. Thus, while in *Bextra* the scales were tipped in favor of the NEJM because of its assertions about the importance of the peer review process in advancing medical knowledge and the critical nature of confidentiality in the peer review process, despite Pfizer's prima facie showing of relevance, here there is such a cloud hanging over the publication of the Article that the PEC should be permitted to uncover the documents sought in the Subpoena in order to expose the Article's academic infirmities and to enable the PEC to discover whether its suspicions about how and why the Article came to be published only in the Journal are true. The Journal here cannot equate itself to the stature of the New England Journal of Medicine.

The PEC's request for an Order compelling the production of research materials is supported by the decision in *Application of American Tobacco Co.*, 880 F.2d 1520 (2d Cir. 1989). In *American Tobacco*, the subpoenas sought all information gathered for the studies and supporting documentation for the studies. While the court found that it was not even clear that there was a scholar's privilege under New York law, it seemed to recognize some level of protection when weighing the burden of production by considering a scholar's interest in his research data. *Id.* at 1528. But here, since Dr. Flythe has produced information as has Fresenius

through the production of custodial files of employees who are co-authors of the Article, the idea that there is a scholar's interest to be protected is weak.

Even if there is such a privilege under New York law, it is qualified, and in reviewing whether to apply the qualified privilege so as to grant the Journal relief, the "court must apply a balancing test to determine whether the need of the party seeking disclosure outweighs the adverse effect such disclosure would have on the policies underlying the [claimed] privilege." *Id.* at 1529, quoting, *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 559 (7th Cir. 1984). According to the *American Tobacco* court, the chilling effect on scientific research caused by pre-publication disclosure was not at issue, as the materials there involved articles *published* years ago. The mere fact that time and effort would be required to comply with a subpoena does not make it unduly burdensome. The court was not swayed by the fact that the researchers were non-parties, as "the publication of their findings and conclusions invites use by persons whom the findings favor and invites reliance by the finders of fact." *Id.* at 1529.

Another case compelling production was *Smith v. Dow Chemical Co.*, 173 F.R.D. 54 (W.D.N.Y. 1997), where the plaintiff sought to compel chemical manufacturers to produce documents related to three ongoing studies that they were sponsoring as members of the Chemical Manufacturers Association. The manufacturers argued that materials were protected by researchers' or scholar's privilege. The Court cited *In re Grand Jury Subpoena Dated Jan. 4, 1984*, 750 F.2d 223 (2d Cir. 1984)[5], noting that the requirements set forth by the Second Circuit were reflected in Fed. R. Civ. P. 26(b)(5), which requires the party asserting a privilege to

[5] In *In re Grand Jury Subpoena*, 750 F.2d 223 (2d Cir. 1984), the Second Circuit stated "the application of a scholar's privilege, if it exists, requires a threshold showing consisting of a detailed description of the nature and seriousness of the scholarly study in question, of the methodology employed, of the need for assurances of confidentiality to various sources to conduct the study, and of the fact that the disclosure requested by the subpoena will seriously impinge upon that confidentiality." *Id.* at 225. The court remanded the matter for the district court to address the privilege issue.

identify the privilege being asserted and each document or communication that is subject to the privilege. *Id.* at 57 (citations omitted). The court found that the defendants had not provided sufficient information (nature of the research, methodology, necessity of confidentiality for sources, whether confidentiality would be impinged by disclosure) to show applicability of the privilege, even if it exists. *Id.* at 58.[6] Also, at least two of the researchers were expected to testify as experts during the trial. Similarly, here the PEC may call the co-authors who are also Defendant's employees as witnesses at trial. *See also*, *Wright v. Jeep Corp.*, 547 F. Supp. 871 (E.D. Mich. 1982), where a non-party researcher was compelled to testify, as his research was relevant to the lawsuit and there was "high probability" that his research results would be used by the plaintiff at trial. The court refused to recognize "a new privilege that would shield academics from testifying." *Id.* at 875.[7]

C. The Journal's Argument That it is Somehow Protected by Egyptian Law Should Be Rejected

The Journal's letter asserts some undefined protection to which it claims it is entitled pursuant to Egyptian law as an additional reason why it should not be required to comply with the Subpoena. But, it does not cite to any authority as to why Egyptian law is applicable here, nor does it even provide the sections of Egyptian law.

However, a simple web search confirms that the Journal has a presence in the United States, at the address where the Subpoena was served. There is no contention by the Journal that

[6] In addition, the court found it significant that the subpoenas were directed at the defendants, rather than the researchers themselves. *Id.* at 58.

[7] The PEC does not contend that under certain circumstances a journal may be entitled to an order quashing a subpoena. The cases that have granted such relief do express sensitivity to the chilling effect on speech that enforcement of the subpoena may have, where an order to produce would be burdensome to the deponent, and where there may be little probative value to the documents sought to be produced. *See, e.g.*, *Cascade Yarns, Inc. v. Knitting Fever, Inc.*, 755 F.3d 55 (1st Cir. 2014); *Cusumano v. Microsoft Corp.*, 162 F.3d 708 (1st Cir. 1998). But the record in such cases differs from the facts here.

service of the Subpoena was improper or not complete. The Journal does business in the United States and received the Subpoena at its New York City address.

The assertion that there is some undefined, abstract protection to which the Journal is entitled under Egyptian law is simply something that the PEC believes the Court should not credit without the Journal meeting a burden of proof. The Journal has not attempted to meet a burden so the assertion should be dismissed as frivolous.

D. Pursuant to Fed. R. Civ. P. 45(f), this Court Can Transfer this Motion to the MDL Court in Massachusetts for Resolution

Pursuant to Rule 45(f), effective December 1, 2013, "When the court where compliance is required did not issue the subpoena, it may transfer a motion under this rule to the issuing court if the person subject to the subpoena consents or if the court finds exceptional circumstances." That amendment to the Rule is consistent with the practice that some federal courts followed when confronted with a motion to compel compliance with a subpoena that was issued by a different federal court, on the ground that the text of Rule 45 "suggests that only the issuing court has the power to act on its subpoenas." *Luppino v. Mercedes-Benz Fin. Serv. USA, LLC*, 2013 WL 1844075, at *4 (E.D. Mich. April 11, 2013) (citations omitted).

Somewhat similarly, in *Patriot Nat. Ins. Group v. Oriska Ins. Co.*, 973 F. Supp. 2d 173 (N.D.N.Y. 2013), another case decided prior to the amendment, the court that issued subpoenas transferred the motion to compel production and cross-motion for protective order to the forum court of the underlying litigation, based on Rule 45.

In *F.D.I.C. v. Axis Reinsurance Co.*, 13 MISC. 380 KPF, 2014 WL 260586 (S.D.N.Y. 2014), where motions to compel compliance with subpoenas were filed in federal court in New York in connection with litigation pending in federal court in Georgia, the motions were transferred to the Northern District of Georgia, based on "considerations of judicial efficiency

and comity." *Id.* at *2. That transferring court also noted that the motions had been filed shortly before amendments to the Federal Rules went into effect, authorizing transfers such as the one at issue. "While judges within this District had transferred motions to compel even before this change took effect..., the new Rule 45(f), and the comments thereto, clearly permit and encourage such action." *Id.* at *3.

Last, it is noteworthy that because this matter involves a Multidistrict Litigation case, the motion may be transferred to the MDL Court, as "enforcing or quashing a subpoena duces tecum is inherent to the authority to supervise pretrial proceedings and 'pretrial depositions' in 'any district,'" as provided in Section 1407. Such a transfer "furthers the goal of judicial economy, one of the underlying purposes of § 1407." *In re Subpoena Issued to Boies, Schiller & Flexner LLP*, 2003 WL 1831426, at *1 (S.D.N.Y. 2003). *See also In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 269 F.R.D. 360 (S.D.N.Y. 2010) (motions to quash filed in North Carolina federal court had been transferred to MDL in New York).

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' motion should be granted and the Journal shall be required to comply with the issued subpoena. In the alternative, Plaintiffs' motion should be transferred to the MDL Court presiding over the GranuFlo Litigation in the United States District Court for the District of Massachusetts.

Respectfully submitted,

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